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510(k) Summary

Manufacturer:	Sulzer Orthopedics Ltd. Grabenstrasse 25 CH 6341 Baar, Switzerland
US Designated Agent:	Sulzer Orthopedics Inc. 9900 Spectrum Drive Austin, TX 78717 Tel: (512) 432-9900 Fax: (512) 432-9291
Contact:	Bruce Waldon Regulatory Affairs Specialist
Classification Name:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353)
Common/Usual Name:	Femoral Stem
Trade/Proprietary Name:	Sulzer Orthopedics CLS Varus/CLS 135 Stem

Product Description:

The CLS 135 Stem is intended for prosthetic replacement of the proximal portion of the femur during total hip arthroplasty for patient conditions of rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, and arthritis secondary to a variety of diseases and anomalies. Other conditions for which this device may be used include avascular necrosis of the femoral head, femoral fractures and fracture dislocation of the hip.

The stem is manufactured from Ti-Al-Nb wrought alloy (Protasul-100™, ISO 5832-11) and is designed for cementless fixation with immediate mechanical stability by a combined medio-lateral and antero-posterior press fit in the cancellous bone of the proximal femur. It is available in 10 sizes. The stem design incorporates a straight taper in the frontal and the sagittal planes, augmented by a series of medially staggered longitudinally tapered ribs on the anterior and posterior proximal stem surfaces. The CLS Varus Stem employs a 12/14 morse-type taper for attachment of a Sulzer metallic or ceramic femoral head having a 12/14 configured bore.

This 510(k) notification incorporates the following line addition to the CLS System: The CLS Varus/CLS 135 stem with a neck angle of 135°, to increase the range of indications to include treatment for large patients or patients with varus hips.

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Intended Use/Indications for Use:

The CLS Varus Stem is intended for non-cemented use to replace the anatomy of the femur in cases of total hip replacement. It is intended to be used with Sulzer Orthopedics acetabular components and metallic or ceramic femoral heads possessing a 12/14 taper.

The indications for use of the CLS Varus Stem are for treatment of the following:

- Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, osteoarthritis; conditions of inflammatory degenerative joint disease (IJD), e.g. rheumatoid arthritis.
- Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- Revision of previously failed hip arthroplasty.

Substantial Equivalence:

The CLS Femoral Stem is substantially equivalent to the previously cleared CLS Femoral Stem as it has the same indications for use, basic design, sizes, materials, sterilization and method of manufacture. Testing and analysis indicated that the device would survive physiological loading.

The CLS Varus Stem is also similar to the original Protek, AG MEM straight stem (K840150), the Sulzer Orthopedics Premier Total Hip Stem (K894051 (cementless)), the DePuy Stature™ stem, and the Zimmer VerSys® stem. All devices are also cementless straight stem designs intended to be press-fit into the proximal femur.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 8 2001

Mr. Bruce Waldon
Regulatory Affairs Specialist
Sulzer Orthopedics Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K010839
Trade Name: CLS™ Varus Femoral Stem/CLS™ 135 Femoral Stem
Regulation Number: 888.3353
Regulatory Class: II
Product Code: LZO
Dated: March 20, 2001
Received: March 21, 2001

Dear Mr.Waldon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010839

Device Name: CLS Varus/CLS 135 Stem

Indications for Use:

The CLS Varus/CLS 135 Stem is intended for prosthetic replacement of the proximal portion of the femur during total-hip arthroplasty without bone cement in treatment of the following:

1. Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, osteoarthritis; conditions of inflammatory degenerative joint disease (IJD), e.g. rheumatoid arthritis.

2. Those patients with failed previous surgery where pain, deformity, or dysfunction persists.

3. Revision of previously failed hip arthroplasty.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010839

Prescription Use ✓ OR Over-The-Counter Use _____

(Optional Format 1-2-96)